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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,298	08/22/2003	Stefan A. Sharpe	PD06063	9222

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER
ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,298	SHARPE ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 21-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 and 21-37 are pending. Applicants have cancelled claims 10-20. Claims 21-37 are new. Claim 1 is currently amended. Receipt and consideration of Applicants' amended claims and arguments/remarks filed on November 17, 2006 is acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 17, 2006 has been entered.

Moot Rejections/objections

All rejections and/or objections of claims 10-20 cited in the previous office action mailed on June 29, 2006 **are moot**, because said claim(s) has/have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8-9, 21-29, 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is vague and indefinite because it requires that the composition within the claimed metered dose inhaler (MDI) be free of a bulking agent. Applicants have defined the term "bulking agent" on pages 6-7 of the specification (i.e. paragraph [0010]) to mean, "an inert substance in which or onto which the active drug ingredient(s) and excipients, if present, are dispersed." This definition is inclusive of the propellant, HFA 227, in the composition within the claimed MDI, because HFA 227 is an inert substance and the active ingredients are clearly dispersed (i.e. suspended) in HFA 227, as evidenced by the language of claim 21 that the composition is a suspension formulation. Suspensions are dispersions. It is immaterial that Applicants have not made direct reference to HFA 227 as a bulking agent.

The remaining claims are rejected for depending from a rejected claim.

Claims 8-9 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: those elements of the metered dose inhaler (MDI) and/or the composition contained therein that yield a percentage of emitted fine particles upon actuation ranging from about 55% to about 85% and having a particle size of less than about 4.7 microns. The language of the cited claims suggest to the reader that the origin of the claimed particle size and percentage of emitted fine particles upon actuation results from three possible sources: (1) features of the MDI, (2) unspecified features of the composition contained within the MDI, or (3) a combination of features of both the MDI and the composition contained therein.

The rejection of claims 1-9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** per Applicants' amendment removing the repugnant phrase, "wherein the formulation is substantially free of a carrier."

Response to Arguments

Applicant's arguments, see page 6, filed November 17, 2006, with respect to the rejection of claims 1-9 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 1-9 under 35 U.S.C. 112, second paragraph has been withdrawn.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-9, 21, 26, 28-30, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Fassberg (U.S. Patent No. 5,474,759).

Applicants claim a metered dose inhaler containing an aerosol suspension formulation consisting of an effective amount of mometasone furoate, a dry powder surfactant, and HFA 227.

Fassberg discloses suspension aerosol formulations in, for example, Example XIX (col. 8, lines 36-40) consisting of **98.8% w/w HFC 227, 0.1% w/w mometasone furoate, 0.1 % w/w PLURONIC® L 121, and 1.0% MIGLYOL® 812 (i.e. surfactant)**. Other similar formulations are disclosed in Examples XX-XXIII (col. 8, lines 41-56) and claims 1-6 and 8-13. Specifically, claim 10 discloses formulations comprising **0.01-1% w/w mometasone furoate, 25-99.99%**

HFC 227 (i.e. 1,1,1,2,3,3,3-heptafluoropropane), 0-75% excipient, and 0-3% surfactant.

Fassberg describes the invented formulations as being directed to compositions that are substantially free of CFC's and are particularly **useful in metered dose-pressurized inhalators** (i.e. MDIs) (col. 1, lines 15-20). The suspensions are made by preferably **pressure filling or cold filling procedures into aerosol containers** (e.g. MDIs) (col. 6, line 66 through col. 7, line 3). It is the Examiner's position that the formulations disclosed by Fassberg are inherently contained within a metered dose inhaler in view of Fassberg's complete disclosure, because it is known that aerosol containers include MDIs. It is impossible for one to formulate pharmaceutical compositions comprising HFC's without using pressurized containers, because under ambient temperature (i.e. ~25 degrees C) and pressure (i.e. ~1 atmosphere) HFC's are gases, whereas in pressurized containers HFC's a liquids. Regarding claims 8-9 and 36-37, it is the Examiner's position that the emitted efficiency and particle size is inherent to the formulations disclosed by Fassberg upon actuation from any MDI. As noted above, claims 8-9 and 36-37 are indefinite as to what aspect of the claimed invention (i.e. the MDI, composition, or both) are responsible for yielding the claimed percent emitted particles and particle size. It is also noted that Fassberg discloses that the particles of the disclosed formulation have a particle size of 1-5 microns (col. 6, lines 25-26) and the value of "about 4.7 microns" reads on a value of 5 microns. Regarding the Markush group of surfactants (e.g. claim 6), Fassberg discloses that soya lecithin is a preferred surfactant (col. 3, lines 40-46). Applicants are reminded that exemplified embodiments are not limiting with regards to the disclosures of a reference.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759) **is maintained** for the reasons of record on set forth on pages 5-7 of the office action mailed on October 26, 2005 and reiterated in the "Response to Arguments" section on pages 5-6 of the previous office action mailed on June 29, 2006. New claims 21-37 are appended to this rejection. In favor of compact prosecution and in anticipation of Applicants' future claim amendments, claims 1, 6-9, 21, 26, 28-30, and 36-37 have been included in the instant rejection. In summary, **claims 1-9 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759)** for the reasons of record as stated above in the instant office action.

Response to Arguments

Applicant's arguments filed November 17, 2006 have been fully considered but they are not persuasive. Applicants have not submitted any substantive arguments as to why the instant rejection is allegedly inappropriate or incorrect. The mere statement of Applicants' belief that the amendments and new claims are allowable is not a persuasive argument. Therefore the Examiner concludes that a person of ordinary skill in the art would have found that claims 1-9 and 21-37 are *prima facie* obvious over the teachings/disclosures of Fassberg because each and every element of the claimed MDIs is taught explicitly or implicitly by the prior art and is thus rendered obvious.

The rejection of claims 1-6 and 8-9 under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (WO 99/51205) in view of Kaplan et al. (U.S. Patent Application 2002/0076382 A1) **is maintained**, for the reasons of record on pages 7-11 of the office action mailed on October 26, 2005 and reiterated in the "Response to Arguments" section on pages 5-6 of the previous office action mailed on June 29, 2006. New claims 21-26 and 28-29 are appended to this rejection. In summary, **claims 1-6, 8-9, 21-26, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (WO 99/51205) in view of Kaplan et al. (U.S. Patent Application 2002/0076382 A1)** for the reasons of record as stated above in the instant office action.

Response to Arguments

Applicant's arguments filed November 17, 2006 have been fully considered but they are not persuasive. Applicants have not submitted any substantive arguments as to why the instant rejection is allegedly inappropriate or incorrect. The mere statement of Applicants' belief that the amendments and new claims are allowable is not a persuasive argument. Therefore the Examiner concludes that a person of ordinary skill in the art would have found that claims 1-6, 8-9, 21-26, and 28-29 are *prima facie* obvious over the combined teachings/disclosures of Dickinson and Kaplan because each and every element of the claimed MDIs is taught explicitly or implicitly by the prior art and is thus rendered obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-5, 7, and 13-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,474,759 **is maintained**, for the reasons of record on pages 11-12 of the office action mailed on October 26, 2005.

The rejection of claims 1, 2-5, and 13-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10, and 12 of copending Application No. 10/967,719 (copending '719) in view of Kaplan et al. (U.S. Patent Application US2002/0076382) **is maintained** for the reasons of record on pages 12-14 of the office action mailed on October 26, 2005.

The rejection of claims 1, 10, and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-7 of copending Application No. 10/649,398 (copending '398) **is maintained** for the reasons of record on pages 14-16 of the office action mailed on October 26, 2005.

The provisional rejection on the ground of nonstatutory obviousness-type double patenting of claims 1-9 as being unpatentable over claims 1-9 and 20-26 of copending Application No. 11/071,078 (copending '078) in view of García-Marcos et al. **is maintained** for the reasons of record set forth on pages 4-5 of the office action mailed on June 29, 2006.

Response to Arguments

Applicant's arguments filed November 17, 2006 have been fully considered but they are not persuasive. Applicants have not submitted any substantive arguments as to why the instant rejection is allegedly inappropriate or incorrect. The mere statement of Applicants' belief that the amendments and new claims are allowable is not a persuasive argument. Therefore the Examiner concludes that above obviousness-type double patenting rejections (provisional and non-provisional) remain proper.

Conclusion

Claims 1-9 and 21-37 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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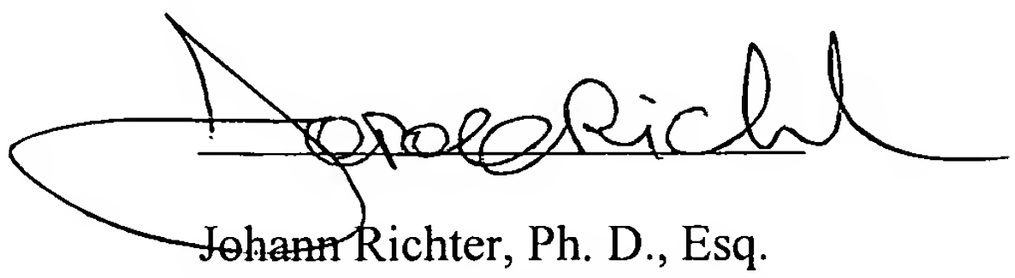

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